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REMARKS

The Invention

The present invention provides a plant transformed with the expression cassette comprising a DNA sequence encoding at least one cell degrading enzyme, e.g., a ferulic acid esterase enzyme, wherein the enzyme is expressed.

Status of the Application

Claims 1-74 are pending in the application. Claims 16-17, 20-22, 24, 26, 34-56 and 58-73 have been cancelled as drawn to a non-elected invention without prejudice and Applicants reserved the right to file further continuation applications on any subject matter disclosed in the instant application or on the subject matter of any previously or presently cancelled claim.

Claim 57 was not listed by the Examiner as having been examined although it belonged to the elected group. Applicants presume that this was an inadvertent omission and that Claim 57 was examined. Applicants will treat Claim 57 as if it were elected and a member of the examined claims.

Claims 1, 3, 13, 14, 23, 25, 57 and 74 have been amended herein. Support for these amendments may be found throughout the specification as filed. Applicants assert new matter has not been introduced by the amendments.

Applicants note that Claims 3-7, 18-19, 30 and 32-33 are deemed to be free of the prior art.

Election/Restriction

Claims 16-17, 20-22, 24, 26, 34-56 and 58-73 have been withdrawn by the Examiner as being drawn to a non-elected invention. Applicants hereby cancel Claims 16-17, 20-22, 24, 26, 34-56 and 58-73 without prejudice. Applicants reserve the right to pursue the originally filed, similar and/or broader Claims in the future.

Claim Objections.

The Examiner has objected to Claims 23 and 74 as depending from non-elected claims. Applicants have amended Claims 23, 57 and 74 to be in independent format. Withdrawal of the objection is respectfully requested.

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The Examiner asserts that Claim 8 does not further limit the process of Claim 1. Applicants respectfully disagree. The DNA constructs of the invention may be introduced into the genome of the desired plant host by a variety of conventional techniques. See, for example, page 10, lines 12 – 17 of the specification. The transformed plant cells which are derived by any of the above transformation techniques can be cultured to regenerate a whole plant that possesses the transformed genotype and thus the desired phenotype such as improved digestibility. See, for example, page 23, lines 3-6 of the specification. Thus, Applicants assert that this objection is in error and respectfully request its withdrawal.

35 U.S.C. §112, first paragraph.

Claims 1-15, 18-19, 23, 25, 27-33, 57 and 74 stand rejected under 35 USC §112, first paragraph as failing to be described in the specification. Specifically, the Examiner asserts that Applicants fail to describe a representative number of polynucleotide sequences encoding a ferulic acid esterase and, furthermore, fail to describe structural features common to the members of the claimed genus, e.g., polynucleotides encoding a ferulic acid esterase. The Examiner has also asserted that Applicants fail to enable any plant comprising an FAE. Applicants respectfully traverse.

Applicants respectfully disagree with the Examiner's arguments. Applicants are NOT required to describe in detail each and every embodiment of the presently claimed invention. Indeed, description of a representative number of species does not require that the Applicants describe each and every species. As indicated in MPEP §2163(II)(A)(3)(a)(ii), "[s]atisfactory disclosure of a 'representative number' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See, e.g., *Eli Lilly*. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces."

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In the instant case, the claims are drawn to a transgenic plant comprising a ferulic acid esterase (FAE). The specification instructs the skilled artisan that an FAE having esterolytic activity may be isolated and characterized using known methods (see US Patent 6,368,833, incorporated by reference in the specification). And, since the specification teaches how to make a ferulic acid esterase (and one skilled in the art using the specification as well as the art available at the filing date of the application could determine, case by case, whether each additional embodiment, each additional ferulic acid esterase, could be made and was operable), the specification is sufficient under 35 USC 112, first paragraph for each and every embodiment of the claimed invention.

Furthermore, a "pioneer" invention is entitled to a broad range of equivalents. *Sealed Air Corp. v. United States International Trade Comm'n*, 68 C.C.P.A. 93, 645 F.2d 976, 984, 209 U.S.P.Q. (BNA) 469, 477 (CCPA 1981). Applicants assert that the present invention is "pioneering," as they are the first to modify the phenolic acid content in various plants. As such, Applicants should be entitled to claims of broad scope. Narrower claims, i.e., claims limited to the exact sequences with no variation, would provide no real protection as the level of skill in this art is so high, art workers could easily avoid the claims. Given the disclosure in the specification, Applicants contend that any skilled artisan could isolate naturally occurring DNA encoding a FAE, construct vectors and transform plant cells, using a variety of promoters and DNA, and could easily determine whether or not the active FAE protein was successfully expressed by the plant cells.

In the alternative, Applicants respectfully submit that the representative number of species disclosed in the present application is more than sufficient to inform those of skill in the enzyme art that Applicants were in possession of the claimed invention, namely, that the expression of a ferulic acid esterase in a transgenic plant enhances digestability. Applicants have incorporated by reference WO 98/14594 which describes enzymes useful in the present invention.

Finally, the Examiner asserts that there might be the need for undue trial and error experimentation. Applicants respectfully disagree. In the instant case, the claims are drawn to a transgenic plant comprising a polynucleotide encoding a ferulic acid

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esterase. The specification must teach how to make/or use each embodiment within the scope of the claims without undue experimentation. And, since the specification teaches how to make a ferulic acid esterase (and one skilled in the art using the specification as well as the art available at the filing date of the application could determine, case by case, whether each additional embodiment, each additional ferulic acid esterase, could be made and was operable), the specification is sufficient under 35 USC 112, first paragraph for each and every embodiment of the claimed invention. Accordingly, reconsideration and withdrawal of the rejections are proper and respectfully requested.

Accordingly, reconsideration and withdrawal of the rejections are proper and respectfully requested.

35 U.S.C. §112, second paragraph.

Claims 2-7, 13, 15, 18-19 and 27-28 are rejected under 35 USC §112, second paragraph as failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner asserts that in Claims 2, 15 and 18 the term "derived" is indefinite, Claims 13, 27 and 28 are unclear, Claims 14 and 25 refer to a portion of a polypeptide rather than a polynucleotide, and Claim 19 lacks proper antecedent basis. Applicants respectfully traverse.

Claims 2, 15 and 18 have not been amended by Applicants. The term "derived" is defined in the paragraph bridging pages 9 and 10. One skilled in the art would understand the meaning of the term given the definition. For example, codon bias may lead to an alteration of a gene sequence for expression in a recombinant construct and/or plant such that the "new" version is derived from the parent. Withdrawal is respectfully requested.

Claim 13 has been amended to clarify the invention. Support for this amendment may be found, for example, in the paragraph bridging pages 11 and 12. Signal sequences may be 3' and/or 5' of the FAE encoding polynucleotide. See page 21, lines 19-26. For example, the endoplasmic reticulum targeting sequence KDEL is 3' to the FAE encoding sequence. See page 21, lines 29-30. It may be in combination with a 5' signal sequence. See Figures 6 and 8. Withdrawal is respectfully requested.

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Claim 19 has been amended to correct the antecedent basis. Withdrawal is respectfully requested.

Claims 14 and 25 have been amended to refer to the ends of the polynucleotides as either 5' or 3', respectively. Support for this amendment may be found, for example, in the paragraph bridging pages 11 and 12. Withdrawal is respectfully requested.

Claims 27 and 28 have not been amended. Applicants comments presented above for Claim 13 are applicable here as well. The paragraph bridging pages 11 and 12 explains "that "target expression" of ferulic acid esterase include sequences located upstream of the FAE coding sequence" (page 11, lines 27-29) and "In addition to upstream signal sequences, the expression cassette of this invention may include a polynucleotide that encodes a signal sequence at the 3' end" (page 12, lines 3-5). Thus, Applicants believe that a skilled person would understand that there may be one or more signal sequences. Withdrawal is respectfully requested.

35 U.S.C. §102(b).

Claims 1, 2, 8 and 23 stand rejected under 35 USC §102(b) as being anticipated by Michelson et al. (US Pat. No. 6,143,543; the '543 patent). Specifically, the Examiner asserts that the '543 patent teaches all the limitations of claims 1, 2, 8 and 23. Applicants respectfully traverse.

It is well-settled law that to anticipate a claim the prior art reference must contain each and every element within the four corners of the document. Thus, Applicants submit that there can be no anticipation unless all of the same elements of the invention are found within the four corners of a single reference. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 USPQ2d 1766, 1767-68 (Fed. Cir. 1987). A reference that merely contains substantially the same elements or only broadly teaches the invention is insufficient to establish anticipation. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 756 F.2d 1556, 1560, 225 USPQ 253, 256 (Fed. Cir. 1985). The Federal Circuit has stated that "anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabling to one of skill in the art." *Bristol-Myers Squibb Co. v. Ben Venue Laboratories Inc.*, 246 F.3d 1368, 1379, 58 USPQ2d 1508, 1516 (Fed. Cir. 2001). Thus, "even if the claimed

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invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." *In re Donohue*, 766 F.2d 531, 533, 226 USPQ 619, 621 (Fed. Cir. 1985), *citing In re Borst*, 345 F.2d 851, 855, 45 USPQ 554, 557 (CCPA 1965), *cert. denied*, 382 U.S. 973, 148 USPQ 771 (1966). Applicants submit that the '543 patent is not appropriate prior art as it fails to enable the skilled person how to make the claimed invention.

Claim 1 has been amended to indicate that the plant expresses an enzyme have ferulic acid esterase activity. It is not enough that the polynucleotide be inserted into the plant genome; expression is required and there must be ferulic acid esterase activity.

The '543 patent broadly describes methods useful in the transformation of plants. However, the methods for expression in plants which they quote are also very generalized and do not take into account many aspects which are needed to achieve correct expression in a plant or which would result in a modified cell wall phenolic composition. Moreover, they are unlikely to be successful (even for their stated aims of enzyme production). For example, the need to remove the intron from the *Aspergillus* genomic sequence, the need to modify the FAE sequence to match the codon usage of plants, the need to target FAE expression to particular cell compartments using signal sequences to achieve cell wall modification in a controlled way are all missing from the '543 patent.

Given the strict standards for anticipation, it is readily apparent that there is no anticipation of the claimed invention in view of '543. Withdrawal of the rejection is respectfully requested.

35 U.S.C. §103.

The Examiner has rejected claims 1-8 and 11-29 as allegedly obvious over the combination of Michelson, *et al.* (US Pat. No. 6,143,543; the '543 patent) in view of Bartolome, *et al.* (Applied and Environmental Microbiology (1997) 63(1):208-212). Applicants respectfully traverse the rejection.

The Examiner has rejected claims 1-8 and 11-29 as allegedly obvious over the combination of Michelson, *et al.* (US Pat. No. 6,143,543; the '543 patent) in view of

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Nichols, *et al.* (US Pat. No. 5,723,764; the '764 patent). Applicants respectfully traverse the rejection.

An essential requirement for a *prima facie* case of obviousness is whether a person skilled in the art would be **motivated** to modify the references to arrive at the **claimed invention**. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988) and *In re Jones*, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992). In particular,

"the examiner must show *reasons* that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the *claimed invention*, would select the elements from the cited prior art references for combination in the manner claimed." *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990)

A *prima facie* case of obviousness requires the Examiner to cite to a combination of references which (a) suggests or motivates one of skill in the art to modify their teachings to yield the claimed invention, (b) discloses the elements of the claimed invention, and (c) provides a reasonable expectation of success should the claimed invention be carried out. Failure to establish any one of these requirements precludes a finding of a *prima facie* case of obviousness and, without more, entitles Applicants to withdrawal of the rejection of the claims in issue. See *e.g.*, *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990); and *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988). Applicants urge that the Examiner has failed to establish not one, but all three requirements as discussed below.

As the '543 patent is the primary reference used for both rejections it will be addressed first.

The '543 patent fails to teach the claimed invention, and neither secondary reference, Bartolome *et al.* or the '764 patent, fails to cure its defects or provide motivation for a transgenic plant that expresses a ferulic acid esterase having ferulic acid esterase activity.

The '543 patent is discussed above. Briefly, the '543 fails to provide an enabling disclosure on how to obtain a transgenic plant that expresses a ferulic acid esterase having ferulic acid esterase activity. An obviousness rejection is inappropriate, where the prior art [gives] either no indication of which parameters [are] critical or no direction as to which of many possible choices is likely to be successful." *In re O'Farrell*, 853

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F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988); *Merck & Co., Inc. v. Biocraft Laboratories, Inc.*, 10 USPQ2d 1843, 1845 (Fed. Cir. 1989). As noted above, the '543 patent is lacking in several critical aspects needed to achieve a transgenic plant that expresses a ferulic acid esterase having ferulic acid esterase activity. For this reason Applicants believe the rejection under §103 is in error and should be withdrawn. For the sake of completeness, however, Applicants will address each of the secondary references as well.

Bartolome *et al.* is not directed to nor does it suggest or teach that recombinant expression of an FAE in plants is desirable. There is no teaching regarding the recombinant expression of xylanase in plants. All Bartolome *et al.* provides is that the treatment of wheat and barley cell walls by exogenous FAE and xylanase, in combination, results in the release of certain dimers. There is no indication of how recombinant expression of an FAE in plants could or even should be accomplished.

Addition of the '764 patent also fails to correct the deficiencies of the '543 patent and does not result in the claimed invention. Although the '764 patent is directed to the expression of bacterial genes related to cellulose biosynthesis there is no discussion regarding the expression of FAE enzymes. There is no suggestion or teaching that the promoters and signal sequences provided by the '764 would be useful. The teachings of the '764 patent certainly do not overcome the deficiencies of the '543 patent.

Applicants believe that, at best, the Examiner presents an "obvious to try" standard in determining the patentability of the present invention, a standard which has been thoroughly discredited. Indeed, as noted above the primary reference fails and cannot be corrected by the addition of the secondary references. Thus, Applicants respectfully request that this rejection be withdrawn and the Claims be passed to allowance.

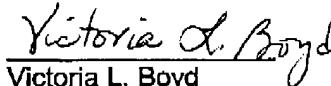
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CONCLUSION

In light of the above amendments, as well as the remarks, the Applicants believe the pending claims are in condition for allowance and issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (650) 846-7615.

Respectfully submitted,
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